Redacted

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

March 22, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
CIN-WL-99-184

James Budiscak, President
Health Services Incorporated
2520 Wales Road, NW
Massilon, Ohio 44646

Dear Mr. Budiscak:

During a FDA inspection on March 3, 1999 of your oxygen transfilling facility, Complete Home Care located at 47 Lincoln Way West, Massilon, Ohio our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21 Code of Federal Regulations, Parts 210 and 211). These deviations cause your medical gases, liquid Oxygen, USP and compressed Oxygen, USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the ACT).

Our investigations revealed the following:

Failure to properly calibrate the Oxygen Analyzer used for the assay of Oxygen, USP in that your firm does not calibrate the "zero" on the meter each day of use. The zero calibration step is performed weekly.

Failure to adequately assay the filled high pressure cylinders of Oxygen, USP for identity and strength prior to release for distribution. Your firm uses a cascade system [redacted] which holds up to [redacted] cylinders for transfilling and your firm fails to test a cylinder from each manifold filling. Testing is performed on only one cylinder per day.

Failure to adequately identify compressed Oxygen, USP with a lot or control number that permits determination of the history of the manufacture and control of the batch. Each manifold filling sequence of compressed Oxygen, USP which represents a separate batch of product is not assigned a separate lot or control number. One lot number is assigned to all cylinders filled during one day.

Failure to assay the incoming compressed oxygen for identity and strength prior to filling compressed oxygen cylinders. No certificate of analysis is received for the incoming compressed oxygen in T size cylinders and the T size cylinders are not tested by your firm for identity and strength before use. In addition, there is no documentation as to when T size cylinders are replaced in the cascade bank of cylinders during the transfilling operation.

Failure to perform adequate prefill operations on each high pressure cylinder prior to filling. Aluminum cylinders filled by your firm are not properly tested in that the dull ring (hammer test) is performed on the aluminum cylinders which could cause possible damage to the cylinders.

Failure to calibrate gauges and thermometers used in the transfilling of compressed Oxygen, USP at suitable intervals in accordance with an established written procedure. There is no documentation showing that pressure gauges, vacuum gauges, and thermometers used in the transilling operation for compressed Oxygen, USP have been calibrated.

Failure to assure that each cryogenic home vessel for liquid oxygen that was sent out for repair/maintenance and returned to the firm for use in the transfilling of liquid oxygen is tested for identity prior to redistribution.

The FDA inspection also revealed that your firm's liquid Oxygen, USP in cryogenic home units is misbranded within the meaning of Section 503(b)(1) of the Act in that its label fails to bear the prescription legend, "Caution: Federal law prohibits dispensing without prescription."

Your firm's liquid Oxygen, USP in cryogenic home units is also misbranded within the meaning of Section 502(b) of the Act in that some of the cryogenic home units do not have your firm's current address listed on their labels.

The above-described violations are not intended to be an all-inclusive list of deficiencies at your facilities. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District